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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,187	06/05/2001	Stuart A. Lipton	P-LJ 4714	5845

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EXAMINER

FALEK, ANNE MARIE

ARTICLE NUMBER PAPER NUMBER

1632

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,187

Applicant(s)

LIPTON ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed March 12, 2002 (Paper No. 8) has been entered.

Claims 1-57 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 12-20, drawn to a method of differentiating progenitor cells and a method of differentiating embryonic stem cells, classified in class 435, subclass 377.
- II. Claims 1-7 and 10-20, drawn to a method of differentiating progenitor cells and a method of differentiating hematopoietic progenitor cells, classified in class 435, subclass 377.
- III. Claim 21, drawn to a method of transplantation, classified in class 424, subclass 93.1.
- IV. Claims 22-30, 33, and 34, drawn to an isolated stem cell, classified in class 435, subclass 325.
- V. Claims 31 and 32, drawn to an isolated embryonic stem cell, classified in class 435, subclass 366.
- VI. Claims 35-37, drawn to an isolated hematopoietic stem cell, classified in class 435, subclass 372.
- VII. Claims 38-41, drawn to a method of identifying a protective or differentiation gene, classified in class 435, subclass 6.
- VIII. Claims 42-49, drawn to a method of identifying a protective gene *in vitro*, classified in class 435, subclass 6.

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IX. Claims 50-57, drawn to a method of identifying a differentiation gene *in vitro*, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and VII-IX are patentably distinct, one from the other, because the inventions are drawn to materially different methods that utilize different starting materials, have different modes of operation, different functions, and different effects. Methods are considered to be patentably distinct when they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). For example, a method of differentiating an embryonic stem cell into a neuronal cell is substantially different from a method of differentiating a hematopoietic progenitor cell into a neuronal cell. The methods require different starting materials, including different cell types having different potentialities, and different modes of operation, including different culture techniques. Thus, the methods of the inventions of Groups I-III and VII-IX are patentably distinct, each from the other.

Inventions IV-VI are patentably distinct, one from the other, because the inventions are drawn to materially different compositions. The cells are different cell types with different potentialities. The different cell types are chemically, biologically, morphologically, and functionally distinct from each other. Thus, the compositions of the inventions of Groups IV-VI are patentably distinct, each from the other.

Inventions I-III and VII-IX are patentably distinct from each of the inventions of Groups IV-VI because although some of the compositions of Groups IV-VI can be used in some of the methods of Groups I-III and VII-IX, their use is not limited to these applications, as they can also be used in a variety of other applications. For example, inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, although the embryonic stem cell of the invention of Group V can be used in the invention of Group I, its use is not limited to this application, as it can also be used to make transgenic animals. Furthermore, although the hematopoietic stem cell of the invention of Group VI can be used in the method of the invention of Group II, its use is not limited to this application, as it can also be used in a method of transplantation. Thus, each of the methods of the inventions of Groups I-III and VII-IX are patentably distinct from each of the compositions of the inventions of Groups IV-VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tiffany Tabb, whose telephone number is (703) 305-1238.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE BAKER
PATENT EXAMINER